

Clinical Trial Protocol

Iranian Registry of Clinical Trials

24 Jul 2026

Assessment of the probiotic effectiveness on the rate of gestational diabetes in comparison to placebo in high risk pregnant women referred to Arash Hospital

Protocol summary

Summary

This study is a double blind randomized, parallel single-center clinical trial which is done in stage two of clinical trial. The aim of this study was to evaluate the effect of probiotic intake on diabetes in pregnancy. Singleton pregnant women aged between 18 -35 year- old enter the study based on inclusion criteria. Our sample size is 572 which are randomly divided into two groups. In intervention group, pregnant women receive probiotic tablets once a day for 10 weeks from 14th week of pregnancy. In control group, placebo is received the same as intervention group. Then, gestational diabetes in both groups is diagnosed by glucose tolerance test. Results of two groups will be compared with each other.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016110111020N6**

Registration date: **2016-12-26, 1395/10/06**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2016-12-26, 1395/10/06

Registrant information

Name

Maryam Khoshideh

Name of organization / entity

Tehran University of Medical Sciences, Arash Hospital

Country

Iran (Islamic Republic of)

Phone

+98 21 7788 0909

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khooshide@tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Tehran University of Medical Science

Expected recruitment start date

2016-12-21, 1395/10/01

Expected recruitment end date

2018-01-21, 1396/11/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Assessment of the probiotic effectiveness on the rate of gestational diabetes in comparison to placebo in high risk pregnant women referred to Arash Hospital

Public title

Effect of probiotic in gestational diabetes

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: singleton pregnant women in the first trimester; BMI more than 25; family history in the first-degree relatives; history of GDM in previous pregnancy; ovarian poly cystic syndrome; history of IUFD birth; Macrosomia; abortion Exclusion criteria: diabetes; heart and CNS diseases; using nerve drugs; multiple pregnancy; positive result of 75 grams glucose test in the first visit

Age

From **18 years** old to **35 years** old

Gender

Female

Phase

2

Groups that have been masked*No information***Sample size**Target sample size: **542****Randomization (investigator's opinion)**

Randomized

Randomization description**Blinding (investigator's opinion)**

Double blinded

Blinding description**Placebo**

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of Tehran University of Medical Science

Street address

Tehran University of Medical Science, Qods Street, Keshavarz Boulevard

City

Tehran

Postal code**Approval date**

2016-10-25, 1395/08/04

Ethics committee reference number

IR.TUMS.MEDICINE.REC.1395.857

Health conditions studied**1****Description of health condition studied**

gestational diabetes mellitus

ICD-10 code

O24.9

ICD-10 code description

Diabetes mellitus in pregnancy, unspecified

Primary outcomes**1****Description**

gestational diabetes

Timepoint

24- 28 weeks of pregnancy

Method of measurement

glucose tolerance test

Secondary outcomes**1****Description**

type of delivery

Timepoint

end of pregnancy

Method of measurement

observational

2**Description**

Macrosomia

Timepoint

After child birth

Method of measurement

weighting

3**Description**

preeclampsia

Timepoint

during pregnancy

Method of measurement

measuring blood pressure and proteinuria

Intervention groups**1****Description**

Intervention group: Patients receive probiotic tablets from 14th week of pregnancy for 10 weeks. Then gestational diabetes is diagnosed by GGT in 24 - 28 weeks.

Category

Treatment - Drugs

2**Description**

control group: Patients receive placebo tablets from 14th week of pregnancy for 10 weeks. Then gestational diabetes is diagnosed by GGT in 24 - 28 week

Category

Treatment - Drugs

Recruitment centers**1****Recruitment center****Name of recruitment center**

Arash Women Hospital

Full name of responsible person

Neda Aslani

Street address

Arash hospital, Rashid street, Tehranpars, Resalat highway

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nedaaslani_363@yahoo.com

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Tehran University of Medical Science

Full name of responsible person

Dr. Maryam Khooshide

Position

obstetrician and gynecologist

Other areas of specialty/work

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, Tehran University of Medical Science

Full name of responsible person

Dr Masoud Younesian

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Tehran University of Medical Science, Qods street, Keshavarz boulevard

City

Tehran

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Vice chancellor for research, Tehran University of Medical Science

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Tehran University of Medical Science

Full name of responsible person

Neda Aslani

Position

gynecologist

Other areas of specialty/work

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Full name of responsible person

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code
empty

Data Dictionary
empty